Optimizing Workload Management in Phase-I Oncology Clinical Research through Novel Oncology - Phase-I Acuity Scoring System (O-PASS)

Shannon E. Fabrie, BS; Matthew Dort, MS, CCRP; Wencesley A. Paez, MD, MS; Teena Kochukoshy, MD, MS; Anthony J. Olszanski, MD, RPh

Background

- The **Ontario Protocol Assessment Level (OPAL)** is widely used to **assess trial acuity** but assigns a uniform score of eight (OPAL = 8) to all Phase-1 trials. This generalization, even after adding "optional elements" score modifiers, **fails to account** for **workload variability** within **Phase-1 programs**, creating **unmet need** for clinical research teams.
- High workloads contribute to burnout among clinical research professionals, highlighting **need** for **workload management tools** tailored to complexities of **Phase-I oncology trials**.
- Optimizing workload management through a dedicated **Oncology – Phase-I Acuity Scoring System (O-PASS)** can help mitigate these concerns and develop a more effective Phase-I program.

Goals

- **O-PASS** was **designed** to more **accurately estimate workload** of Phase-I oncology clinical research coordinators (CRCs) and clinical research nurses (CRNs).
- By improving workload distribution, **O-PASS aims** to **reduce burnout** and **turnover**, ultimately stabilizing staffing and strengthening the Phase-I program to expand patient access to clinical trials.

Solutions & Methods

Step 1: Standard Acuity Scoresheet

Assess each study within the portfolio and pass through the following criteria totaling each item to a final raw acuity score per study. The raw acuity score will have a maximum of 100.

Examples of Standard Acuity Scoresheet Metrics	
Estimated Total Enrollment Per Year	Outpatient Clinic Observation Period Lengths and In-Patient Admission Observations
Number of Visits During Dose Limiting Toxicity Period	Number of Investigational Products
Number of Visits Post Dose Limiting Toxicity Period	Treatment Schedule
Requires Coordination with Outside Departments (i.e.. Interventional Radiology/Radiation Therapy/Surgery)	CRS/ IRR/ SAE Risk Assessment
Central Lab Collection Time-Points	Number of Unique Cohorts

Standard Scoring Levels: 0 = N/A; 1 = Not Difficult; 2 = Somewhat Difficult; 3 = Moderately Difficult; 4 = Very Difficult; 5 = Most Difficult

Step 2: Raw Acuity to Weighted Score

convert raw acuity score from Step 1 to Standard Weighted Score

Raw Acuity Score	Weighted Study Score
<60	1-Point Study
60-70	2-Point Study
70-100	3-Point Study

Step 3: Workload Calculation Key

Make study specific adjustments per accrual status and whether staff member is primary CRC/CRN or primary-backup CRC/CRN. Calculate total workload.

Adjustment Key:
0.25 weighted points: Closed to Accrual/No Patient Studies
(Weighted Score/2): Closed to Accrual/Patients Still On Study
(Weighted Score/4): Primary Back Up CRC/CRN

Total Workload Score =
[Sum of All Primary Assigned Studies Weighted Scores] + [Sum of (Each Primary Back Up Study Weighted Score/4)]

Step 4: Assign Studies with Maximum Workloads per Level of Experience

CRC/CRN total workload should not exceed level of experience or ability per position.

Position	Years of Experience	Max Study #	Max Total Workload Score
CRN III	~ 4 years' experience as a Clinical Research Nurse	8-9 Studies	13-14 Weighted Score
CRC III	~ 4 years' direct experience in Clinical Research	7-8 Studies	12-13 Weighted Score
CRN II	~ 2 years' experience as a Clinical Research Nurse	6-7 Studies	11-12 Weighted Score
CRC II	~ 2 years' experience as a Clinical Research Coordinator or 5 years of experience related clinical research role	5-6 studies	9-11 Weighted Score
CRN I	~ 1 year experience as a Clinical Research Nurse or ~ 2 years' experience in nursing with a focus in oncology	4-5 studies	9-10 Weighted Score
CRC I	~ 1 year experience as a Clinical Research Coordinator or ~ 2 years' experience in healthcare setting	3-4 studies	7-9 Weighted Score

Outcomes

- **67% of CRC/CRNs** reported **improved work-life balance** and **reduced burnout**.
- **100% believed** O-PASS could **help reduce staff turnover**

Lessons Learned and Future Considerations

- Preliminary data suggests **O-PASS enhanced the FCCC Phase-I clinical research program** at FCCC.
- **Limitations of study include:**
  - Small cohort size
  - Single institution setting
  - Concurrent staffing changes may have influenced results.
- Ongoing **follow-up questionnaires** will further assess **long-term effects**; management will **analyze retention data** to **evaluate** its **impact on turnover.**
- Further **refinement of tool** will **increase effectiveness**. In the future, O-PASS will serve as **model for workload assessment tools** for **data specialists and regulatory coordinators.**